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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,279	09/06/2000	Jiangchun Xu	210121.427CIP	9953

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EXAMINER
SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
1634	18

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/657,279	Xu et al.
Examiner	**Art Unit**
Jehanne Souaya	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Aug 30, 2002 .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 18-35 is/are pending in the application.

4a) Of the above, claim(s) 18-26 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 27-35 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on Aug 30, 2002 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 18 17
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 1-17 have been canceled. For the purposes of expediting prosecution, claims 18-26, contained in the response filed April 18, 2002 have been withdrawn from consideration, without prejudice to prosecution of any subject matter in a related application, at applicants request. Claims 18-26, contained in the response filed August 30, 2002 have been renumbered as claims 27-35. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied (necessitated by amendment) or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

Drawings

2. The new corrected drawings have been reviewed. Some of the drawings contain amino acid sequences that are not designated by SEQ ID NOS in either the drawing or the "Brief Description of the Drawings", for example, see Figures 8 and 9. Nucleic acid and polypeptide sequences contained in the specification must be designated by a SEQ ID NO. See MPEP, chapter 2400. Appropriate correction is required.

Maintained Rejections

Claim Rejections - 35 USC § 112

3. Claims 28-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising the amino acid sequence of SEQ ID NO 108, a fusion protein comprising a polypeptide comprising the amino acid sequence of SEQ ID NO 108, does not reasonably provide enablement for: 1) a fragment comprising at least 10 consecutive or at least 20 consecutive amino acid residues of SEQ ID NO 108, 2) an isolated polypeptide comprising at least 75%, 85% or 95% identity to the entirety of SEQ ID NO 108, 3) an isolated polypeptide having at least 90% identity to an amino acid sequence comprising at least 20 consecutive amino acid residues of SEQ ID NO 108, 4) an isolated polypeptide having at least 95% identity to an amino acid sequence comprising at least 10 consecutive amino acid residues of SEQ ID NO 108, or 5) a fusion protein comprising any of 1-4 above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are broadly drawn to mutants, variants and homologs of the polypeptide of SEQ ID NO 108 as well as polypeptides comprising fragments of the polypeptide of SEQ ID NO 108, from any source, which have not been taught in the specification. The specification teaches the polypeptide of SEQ ID NO 108 as well as the nucleic acid sequence of SEQ ID NO 107, which encodes the polypeptide of SEQ ID NO 108. The specification teaches that the polynucleotide of SEQ ID NO 107 was over expressed in 60% of prostate tumors, detectable in normal kidney, but not detectable in all other tissues tested, including normal prostate tissue (p. 125, line 16-page 126 line 5). The specification teaches that the polypeptide of SEQ ID NO 108

was expressed in 5 out of 5 prostate carcinoma samples tested, and that the staining pattern of anti-P504S antibodies (P504S is the polypeptide of SEQ ID NO 108) in benign prostate cells was a light nuclear staining while that of prostate carcinoma samples was a cytoplasmic granular staining. The specification teaches that SEQ ID NO 108 was expressed in some normal tissues, such as kidney liver, and brain but not all. The specification teaches that based on the differential expression of SEQ ID NO 108, it could be useful in the diagnosis of prostate cancer. Although the specification teaches how to make and use the polypeptide of SEQ ID NO 108, the specification does not enable the skilled artisan to make or use variants, homologs, or mutants of SEQ ID NO 108, from any source. The specification teaches that cDNA splice variants of P504S were found (SEQ ID NOS 600-605), however the specification does not teach the function of any of these splice variants, nor whether they were over expressed in prostate tumor samples vs normal prostate tissue.

Polypeptides encompassed by the claims, such as: 1) a fragment comprising at least 10 consecutive or at least 20 consecutive amino acid residues of SEQ ID NO 108, 2) an isolated polypeptide comprising at least 75%, 85% or 95% identity to the entirety of SEQ ID NO 108, 3) an isolated polypeptide having at least 90% identity to an amino acid sequence comprising at least 20 consecutive amino acid residues of SEQ ID NO 108, 4) an isolated polypeptide having at least 95% identity to an amino acid sequence comprising at least 10 consecutive amino acid residues of SEQ ID NO 108, or 5) a fusion protein comprising any of 1-4 above; include a large number of mutants, variants, and homologs of SEQ ID NO 108, resulting from missense,

frameshift and truncation mutations, from any source, which have not been taught in either the specification or the art. Neither the specification, nor the art teach that any of these mutants, variants, or homologs of SEQ ID NO 108 could be used to identify prostate cancer. Further, since the specification does not teach the activity or function of the polypeptide of SEQ ID NO 108 or how it relates to prostate cancer, the skilled artisan would not be able to establish a predictable correlation as to the function of such mutants, variants, or homologs to determine whether they could also be used to identify prostate cancer, without undue experimentation. In addition, because the specification does not teach the activity or function of SEQ ID NO 108, the skilled artisan would not be able to determine which molecules encompassed by the broadly claimed invention would have retained or altered biological activity and it would further be unpredictable as to how the skilled artisan could modify the molecule without altering it's biological activity.

A sequence search revealed that SEQ ID NO 107 has 97.1% identity to the cDNA encoding peroxisomal-methylacyl-CoA racemace which is the enzyme responsible for the conversion of pristanoyl-CoA and C27-bile acyl-CoAs to their (S) stereoisomers (see Ferdinandusse et al, Nature Genetics, vol. 24, 2000, pp 188-191). Ferdinandusse teaches, however, that mutations in this gene are associated with adult onset sensory motor neuropathy, and does not teach any association between this gene and prostate cancer, while the specification, does not teach or suggest the use of the claimed polypeptides with adult onset sensory motor neuropathy, does not teach the function or biological activity of the polypeptide of SEQ ID NO

108 and specifically teaches that no significant homologies were found with SEQ ID NO 107 and the EMBL and GenBank databases (p. 120, lines 15-16). Therefore, based on the lack of guidance from the specification or the art, the skilled artisan would not be able to determine a predicable correlation between variants, mutants, or homologs of the polypeptide of SEQ ID NO 108 and an association to prostate cancer.

A correlation between mutants, variant and homologs encompassed by the claims and a specific biological activity and it's association to prostate cancer is clearly unpredictable in light of the lack of guidance from the specification and the state of the art with regard to the specific biological function of the polypeptide encoded by SEQ ID NO:108. Since the specification does not teach the specific biological function or activity of the polypeptide of SEQ ID NO 108, and neither the specification nor the art teach how the function of the polypeptide is associated to prostate cancer nor how the skilled artisan could modify the polypeptide of SEQ ID NO 108 to obtain a polypeptide with either retained or modified function in association with it's differential expression in prostate cancer, the skilled artisan would be required to perform undue experimentation to make or use the biologically active or altered polypeptides encompassed by the broadly claimed invention. To practice the invention as broadly as it is claimed, the skilled artisan would first have to determine the function of the polypeptide of SEQ ID NO 108 and it's association to prostate cancer. The skilled artisan would then have to determine what amino acid residues were associated with the expression of the polypeptide in relation to prostate cancer, and then would have to determine which amino acids could be modified to either retain biological

function or to result in a protein with altered function. Given that the art teaches that a single amino acid change can alter the function of a biomolecule (see Proudfoot et al, Journal of Biological Chemistry, vol. 271, pp 2599-2603, which teaches that extension of recombinant human RANTES by a single residue [Met-RANTES] at the amino terminus was sufficient to produce a potent and selective antagonist - see abstract) and that some of these changes are unpredictable, and given that the specification does not teach the function of the polypeptide of SEQ ID NO 108 and it's association to prostate cancer such analyses would require trial and error, thus constituting undue experimentation. It is noted that because the skilled artisan would be required to perform undue experimentation to make and use the polypeptides of claim 2, undue experimentation would also be required to make or use fusion proteins comprising the polypeptide of claim 2.

Response to Arguments

The response traverses the rejection. The response asserts that the specification teaches making and using fragments and variants of applicants cancer associated sequence. This argument has been thoroughly reviewed but was not found persuasive. With regard to using the claimed polypeptides, although the specification teaches differential expression patterns of SEQ ID NO 108 in prostate carcinoma versus benign prostate cells, the specification does not teach the use of variants, mutants or homologs of SEQ ID NO 108, from any source, in the detection of prostate cancer. Neither the specification nor the art teach that variants, mutants, or homologs of SEQ ID NO 108 can be used to differentiate prostate cancer cells from benign prostate cells.

Without such a teaching, the skilled artisan would not be able to establish a predictable correlation between the use of variants, homologs, or mutants of SEQ ID NO 108, from any source, to detect prostate cancer, without trial and error analysis. As the results of such analysis are unpredictable, this is considered undue experimentation. The response further asserts that it is the prostate tumor associated expression profile of SEQ ID NO 108, and not it's biological function, that is most pertinent to the enablement of the presently claimed invention. This argument has been thoroughly reviewed but was not found persuasive. The claimed products are drawn to mutants, variants, and homologs of SEQ ID NO 108. The biological function of the polypeptide of SEQ ID NO 108 is not irrelevant and is critical for the skilled artisan to be able to identify proteins which would be variants, mutants, or homologs of SEQ ID NO 108. As the specification does not teach the function of the polypeptide of SEQ ID NO 108, it would require undue experimentation for the skilled artisan to determine which amino acids could be altered to make polypeptides that would result in proteins with altered or retained biological activity as that of the protein of SEQ ID NO 108. The response asserts that upon accepting that SEQ ID NO 108 can be used to make prostate cancer specific diagnostic antibodies, the skilled artisan would also understand that claimed fragments and variants of SEQ ID NO 108 could be used in the same context. This argument has been thoroughly reviewed but was found unpersuasive because the specification has not taught antibodies that would recognize the claimed fragments, variants, mutants, and homologs of SEQ ID NO 108 and still be used to identify prostate cancer. Antibodies to fragments, variants, mutants, and homologs of SEQ ID NO 108 would not

necessarily recognize SEQ ID NO 108 and it would be unpredictable as to whether such would be capable of use in a method of identifying prostate cancer.

Written Description

4. Claims 28-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to mutants, variants and homologs of the polypeptide of SEQ ID NO 108 as well as polypeptides comprising fragments of the polypeptide of SEQ ID NO 108, from any source, which have not been taught in the specification. The specification teaches the polypeptide of SEQ ID NO 108 as well as the nucleic acid sequence of SEQ ID NO 107, which encodes the polypeptide of SEQ ID NO 108. The specification teaches that the polynucleotide of SEQ ID NO 107 was over expressed in 60% of prostate tumors, detectable in normal kidney, but not detectable in all other tissues tested, including normal prostate tissue (p. 125, line 16-page 126 line 5). The specification teaches that the polypeptide of SEQ ID NO 108 was expressed in 5 out of 5 prostate carcinoma samples tested, and that the staining pattern of anti-P504S antibodies (P504S is the polypeptide of SEQ ID NO 108) in benign prostate cells was a light nuclear staining while that of prostate carcinoma samples was a cytoplasmic granular staining. The specification teaches that SEQ ID NO 108 was expressed in some normal tissues, such as kidney liver, and brain but not all. The specification teaches that based on the differential expression of

SEQ ID NO 108, it could be useful in the diagnosis of prostate cancer. The specification, however, does not teach the biological function of the polypeptide of SEQ ID NO 108. The specification teaches that cDNA splice variants of P504S were found (SEQ ID NOS 600-605), however the specification does not teach the function of any of these splice variants, nor whether they were over expressed in prostate tumor samples vs normal prostate tissue.

Polypeptides encompassed by the claims, such as: 1) a fragment comprising at least 10 consecutive or at least 20 consecutive amino acid residues of SEQ ID NO 108, 2) an isolated polypeptide comprising at least 75%, 85% or 95% identity to the entirety of SEQ ID NO 108, 3) an isolated polypeptide having at least 90% identity to an amino acid sequence comprising at least 20 consecutive amino acid residues of SEQ ID NO 108, 4) an isolated polypeptide having at least 95% identity to an amino acid sequence comprising at least 10 consecutive amino acid residues of SEQ ID NO 108, or 5) a fusion protein comprising any of 1-4 above; include a large number of mutants, variants, and homologs of SEQ ID NO 108, resulting from missense, frameshift and truncation mutations, from any source, which have not been taught in either the specification or the art. Neither the specification, nor the art teach that any of these mutants, variants, or homologs of SEQ ID NO 108 could be used to identify prostate cancer. Further, since the specification does not teach or describe the activity or function of the polypeptide of SEQ ID NO 108 or how it relates to prostate cancer, the skilled artisan would not be able to determine which molecules encompassed by the broadly claimed invention would have retained or altered biological activity. Therefore, since the specification does not teach or describe the

activity or function of the polypeptide of SEQ ID NO 108 or how it relates to prostate cancer, the disclosed structural feature of SEQ ID NO 108 does represent a substantial portion of the claimed genus of polypeptides.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of a polypeptide comprising the amino acid sequence of SEQ ID NO 108 or a fusion protein comprising such , the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Applicant should note that because the polypeptides of claims 28-34 do not meet the written description requirement, a fusion protein comprising such polypeptides also lack written description.

Response to Arguments

The response traverses the rejection. The response asserts that biological function is only one example of identifying characteristics to support a claimed genus of polypeptides and that an illustrative sufficient and relevant identifying characteristic shared by members of the currently claimed genus is their ability to be used in the detection of prostate cancer. The response further asserts that the disclosure in the specification teaches splice variants of SEQ ID NO 108 and therefore the skilled artisan would recognize that applicants were in position of more than the sequence of SEQ ID NO 108 and that sequences having 75%, 85%, or 95% identity to SEQ ID NO 108 could be used to generate antibodies having specificity for a polyeptide sequence of SEQ ID NO 108. This argument has been thoroughly reviewed but was not found persuasive.

Although the specification teaches splice variants of SEQ ID NO 108, the previous office action explained that the specification did not teach any differential expression patterns for such splice variants. Therefore, the skilled artisan would not be able to determine that applicants were in possession of more than one polypeptide capable of identifying prostate cancer in a large genus of polypeptides encompassed by the claimed mutants, variants and homologs of the instant invention. While the specification teaches that SEQ ID NO 108 can be used to identify prostate cancer, the specification has not taught homologs of SEQ ID NO 108, for example, that are capable of use in the same manner. Absent a teaching of any other relevant, identifying characteristics of SEQ ID NO 108, such as function, the specification does not demonstrate possession of mutants, variants, or homologs of SEQ ID NO 108 with either retained or altered biological activity, or capable of identifying prostate cancer.

14. Claims 17-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of copending Application Nos. 09/568,100, 09/636,215, 09/593,793, and 09/605,783. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 2 of the '100, '215, '793, and '783 applications recites in the alternative "an isolated polypeptide which comprises an amino acid sequence that is encoded by a polynucleotide sequence recited in SEQ ID NO 107". The claims of the instant application are drawn to a polypeptide comprising an amino acid

sequence of SEQ ID NO 108. Therefore, the claims of the instant application and claim 2 of the '100, '215, '793, and '783 applications are coextensive in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

The response acknowledges the provisional double patenting rejection but does not traverse it. The rejection is made FINAL.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

5. Claims 28, 29, 33, and 34 are rejected under 35 U.S.C. 102(a) as being anticipated by Accession number CAA69358 (September 15, 1997).

Accession number CAA69358 teaches a sequence which contains amino acids at position 242-278 which are identical (except for position 255 of CAA69358) to amino acid residues 263-299 of SEQ ID NO 108 (longest sequence of consecutive, identical amino acids is 22 residues). With regard to claims 33 and 34, the claims have been broadly interpreted to mean that a specific portion of a polypeptide from CAA69358 has 90% identity to 20 consecutive amino acids from SEQ ID NO 108 or 95% identity to 10 consecutive amino acids from SEQ ID NO 108.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over accession number CAA69358 in view of Haldenwang (WO 93/03156).

Accession number CAA69358 teaches a sequence which contains amino acids at position 242-278 which are identical (except for position 255 of CAA69358) to amino acid residues 263-299 of SEQ ID NO 108 (longest sequence of consecutive, identical amino acids is 22 residues). With regard to claims 33 and 34, the claims have been broadly interpreted to mean that a specific portion of a polypeptide from CAA69358 has 90% idenity to 20 consecutive amino acids from SEQ ID NO 108 or 95% identity to 10 consecutive amio acids from SEQ ID NO 108. Although

accession number CAA69358 does not teach a fusion protein comprising the polyeptide, Haldenwang teaches that expression of heterologous proteins fused with protein stabilization sequences makes it possible to produce the protein from prokaryotic hosts (see p. 6, lines 30-35). Therefore, it would have been prima facie obvious to one of ordinary skill in the art to construct a fusion protein comprising the protein taught by accession number CAA69358 with a protein stabilization sequence for the purpose of producing the protein in a prokaryotic host, which the ordinary artisan would have recognized was a way to produce the protein taught by CAA69358. Methods of making fusion proteins were well known in the art at the time of the invention, as exemplified by the teachings of Haldenwang.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. No claims are allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

Jehanne Souaya
Jehanne Souaya
Patent examiner
Art Unit 1634
11/14/02